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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,669	07/12/2000	Bruce Ernest Tepper	8168	2159

27752 7590 02/19/2003

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/19/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

614,664

Applicant(s)

TEPPER et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/11/03 & 11/18/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 5-8, 10-11, 13-20 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 5-8, 10-11, 13-20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 15
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The amendment of 11/18/02 has entered no new matter. Claims 1, 5-8, 10-11 and 13-20 are pending and under examination.

The following corrections have been entered in the Office copy of the action mailed 4/2/02 (Paper 10):

On form PTO-326 under "Disposition of claims" changed both recitations of "6-11" to --5-11--.

At page 2, line 2, changed "4-11" to --5-11--.

At page 3, line 6, changed "1-20" to 1, 5-11 and 13-20--.

At page 5, line 15 (not counting fine print after line 14) changed "1-20" to --1, 5-11 and 13-20--.

These changes have been entered in red ink and initialed and dated by the examiner.

Applicant's amendment has overcome previously stated objections to claims 8-9 under 37 CFR 1.75 (c).

112, second paragraph rejections are maintained or newly stated herein below, as applicable to the amended claims.

Claims 1, 5-8, 10-11, and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 20, last line of each, recitation of "the condition (e.g. response)" is indefinite. Firstly, the phrase is indefinite by reciting an exemplary embodiment in parentheses;

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Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

February 3, 2003

*spurious when
of page 8*

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see MPEP 2173.05 (d). Secondly, the fact that applicant has recited "response" as an exemplary embodiment of "condition" means that applicant must consider "response" to be narrower than "condition". Recitation of "condition" in the concluding step of each claim is unclear because the commencement of the step recites "assessing the response" (claim 1) or because previous steps refer to assessing various "responses" (claim 20).

In claim 1, last line recitations of "comparing" and of plural "test sites" are unclear. The previous lines of the claim refer only to a singular "test site" and a singular "response". If there is only one "test site" and one "response" in the claim steps, how then can there be any "comparing"? What is the "response" compared against?

The above rejections pertaining to claims 1 and 8 have been necessitated by virtue of what applicant has inserted by amendment into claims 1 and 8.

Applicant's amendment and urgings have overcome previously stated rejections pertaining to indefiniteness in claims 1, 8 and 9.

Claims 16-20 are unclear as to how the patch of claim 15 would be applied to the cell cultures of claim 16. Applicant has asserted that one of skill would understand how this is accomplished. The examiner does not concur because one of skill would understand a "patch" as something to be applied to the skin of an organism (e.g. like a Band-Aid). One of skill would not know if applying such a "patch" even adhere to the culture without disrupting the cellular mass?

Applicant's amendment has overcome the previously stated rejection under 35 U.S.C.

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Prior art rejections of record are maintained.

Claims 1 and 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kapadia et al. (5,935,581) for reasons of record in Paper 16; and as discussed further below.

Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Fruehauf et al. (6,008,007) for reasons of record in Paper 16 and as discussed further below.

The two references of record will only be further discussed to the extent that their teachings are shown to be consistent with the terms of applicant's claims, as these terms are defined at specification pages 3-6.

The rejection over Kapadia et al. has been maintained only from claim 1 and various dependents. The rejection has been withdrawn for claim 8 and any of its dependents. Kapadia et al. do not show the invention of amended claim 8 for the following reasons.

1) Given that application of the tumor initiator of DMBA to a site on the skin constitutes a "primary challenge" and that UV irradiation of the site constitutes a "secondary challenge" (Paper 10, pages 6 and 7) Kapadia et al. do not show step c) of instant claim 8; they only show assessing step d) of instant claim 8.

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2) Given the above interpretation of what constitutes the primary and secondary challenges, Kapadia et al. do not show any of the controls recited in step b) of instant claim 8, in accord with the definitions of these controls at specification page 6. Since none of these controls exist, Kapadia et al. do not conduct step e) of instant claim 8.

The test compound (e.g. a food colorant) that is being tested for its inhibition of tumor promotion may be properly considered as a "post--challenge intervention", given the extremely broad definition of such at instant specification page 4. Thus claim 6 is properly included in the rejection. Claim 7 has been properly included, since Kapadia et al. Teach the determination of the "incidence of papillomas" (col. 23, lines 12, 31 and 45) at the test site would include a visual assessment.

With respect to Fruehauf et al., the control cell cultures that have not been exposed to a chemotherapeutic drug (corresponding to the instant primary challenge) constitute "secondary controls", as defined at instant specification page 6. The controls exposed to zero by radiation constitute "primary controls", in accord with applicant's definition at instant

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specification page 6. See portion of Fruehauf et al. previously noted. Claim 8 is thus properly included in the rejection.

Applicant has merely traversed the prior art rejections over Kapaidia et al. and Fruehauf et al. by vaguely arguing that they do not show what applicant claims. This is not convincing because the previous Office action has clearly set out how each of these references show a method involving both a primary challenge and a secondary challenge. Applicant has set forth no specific arguments as to why the tumor initiator and UV irradiation of Kapadia et al. fail to constitute primary and secondary challenges, as instantly defined. Likewise applicant has not specifically argued why the sensitizing/chemotherapeutic agent and radiation of Fruehauf et al. fail to constitute a primary challenge and a secondary challenge. That applicant may not have envisioned the particular embodiment of Kapaidia et al. and Fruehauf et al. when he wrote the specification and claims makes no difference. The definitions of the claim terms given in the specification are extremely broad and the examiner has applied the references in accord with interpreting the claims according to their broadest reasonable scope. Applicant's urgings are not commensurate with the scope of the claimed invention.

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Applicant's urgings filed on 11/18/02 have been considered but are not convincing of patentability.

No new reference has been cited; therefore this action is made final.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A.

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Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

February 3, 2003

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 *1644*